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EXAMINER	
YABUT, DIANE D	
ART UNIT	PAPER NUMBER
3734	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/734,929	GINN ET AL.	
	Examiner	Art Unit	
	DIANE YABUT	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 September 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20 and 22-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20 and 22-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is in response to applicant's amendment received on 09/15/2009.

The examiner acknowledges the amendments made to the claims.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Freeman et al.** (U.S. Patent No. **6,306,114**) in view of **Brucker** (U.S. Patent No. **6,296,657**).

Claims 1-2 and 4-10: Freeman et al. disclose a biocompatible plug body **10** comprising a proximal end and distal end, the body comprising a lumen **18** extending between the proximal end and the distal end, and a biocompatible sealing member ("valve") **20a-e**, which may be annularly-shaped, disposed within the lumen that is expandable across the lumen when exposed to fluid for substantially sealing the lumen from fluid flow therethrough, wherein the biocompatible body does not expand when exposed to the fluid and wherein the sealing member does not extend outside the plug member lumen (see abstract; Figures 1-8). The sealing member is also biased towards a first ("closed") configuration for substantially sealing the lumen from fluid flow therethrough in either direction of the lumen, and is movable to a second ("open")

configuration for accommodating introduction of one or more devices through the lumen. Freeman et al. also disclose a connector on the proximal end of a biocompatible body for detachably securing the body to a delivery device or elongate member shaft **160** (Figure 14). The body has a length of not more than about ten millimeters and a diameter being not more than about twice the length (col. 6, lines 40-45).

Freeman et al. does not expressly disclose a bioabsorbable material for the device. However, Freeman et al. discloses a silicone, biocompatible material (col. 3, lines 65-67) and that the plug may be made of any "other suitable materials known to those skilled in the art" (col. 7, lines 11-14). Brucker also teaches a plug made of bioabsorbable materials (abstract, col. 5, lines 26-33). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a bioabsorbable material to the plug of Freeman et al., as taught by Brucker, depending on the patient and the condition if a temporary occlusion is desired without necessitating removal.

Claim 3: Freeman et al. disclose the claimed device except for the sealing member comprising an expandable gel foam.

Brucker teaches a sealing member **71** comprising an expandable gel foam that is expandable when exposed to the fluid to substantially seal the lumen (Figure 7; col. 5, lines 7-18). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the sealing member of Freeman et al. by providing an expandable gel foam that is expandable when exposed to fluid, as taught by Brucker, since it was well known in the art for facilitating selective expansion of a sealing member when placed in a wound.

3. Claims 11-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Freeman et al.** (U.S. Patent No. **6,306,114**) in view of **Brucker** (U.S. Patent No. **6,296,657**) and **Hermann et al.** (U.S. Patent No. **5,871,474**).

Claims 11-18: Freeman et al. disclose the claimed device (as mentioned above in paragraph 3), including a sealing member **20a** being disposed adjacent a wide end **22** of the lumen (see Figures 1 and 6) and being movable into a smaller diameter portion **24** of the lumen for substantially sealing the lumen from fluid flow therethrough and comprising a flexible material that may be wedged into the tapered portion (Figure 5), except for a bioabsorbable material and the lumen comprising a tapered portion that tapers in cross-section and the sealing member comprising a coil of material.

Freeman et al. does not expressly disclose a bioabsorbable material for the device. However, Freeman et al. discloses a silicone, biocompatible material (col. 3, lines 65-67) and that the plug may be made of any "other suitable materials known to those skilled in the art" (col. 7, lines 11-14). Brucker also teaches a plug made of bioabsorbable materials (abstract, col. 5, lines 26-33). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a bioabsorbable material to the plug of Freeman et al., as taught by Brucker, depending on the patient and the condition if a temporary occlusion is desired without necessitating removal.

Hermann et al. teach a plug member with a tapered lumen (Figure 6b). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide a tapered lumen portion to Freeman et al. in order to better conform to the tissue passage and therefore provide a more effective sealing device. In addition,

although the sealing member of Hermann is not comprised of a coil of material, Hermann does teach screw threads **12** which may take the form of a coil and increase the traction of the sealing member within the body to effectively keep it in place, and therefore it would have been obvious to one of ordinary skill in the art to modify the sealing member of Freeman et al. to a coil of material for increased traction and therefore a more securely sealed plug.

4. Claims 19-20, 22-25, 27-28, and 32-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Freeman et al.** (U.S. Patent No. **6,306,114**) in view of **Brucker** (U.S. Patent No. **6,296,657**) and **Atkinson** (U.S. Patent No. **6,645,225**).

Claims 19-20, 22-25, 27-28, and 32-35: Freeman et al. disclose the claimed device (as mentioned above in paragraph 3), except for the bioabsorbable material or the plug member lumen being in fluid communication with the elongate member lumen and the plug member lumen having a tapered portion reducing in cross-section, and a second elongate member comprising a location indicator.

Freeman et al. does not expressly disclose a bioabsorbable material for the device. However, Freeman et al. discloses a silicone, biocompatible material (col. 3, lines 65-67) and that the plug may be made of any "other suitable materials known to those skilled in the art" (col. 7, lines 11-14). Brucker also teaches a plug made of bioabsorbable materials (abstract, col. 5, lines 26-33). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a bioabsorbable

material to the plug of Freeman et al., as taught by Brucker, depending on the patient and the condition if a temporary occlusion is desired without necessitating removal.

Atkinson teaches a plug member **26** having a tapered lumen **36** being in fluid communication with an elongate member lumen **43** with cooperating connectors **44** and **38** and an actuator **46** for releasing the plug member from the distal end of the elongate member (Figure 7). It would have been obvious to one of ordinary skill in the art at the time of invention to provide communicating plug and elongate member lumens, as taught by Atkinson, to Freeman et al. in order to allow the assembled delivery combination of the elongate member and the plug to be aligned within the patient's body by sliding over an element such as a J-wire (col. 6, lines 7-11). It would have also been obvious to one of ordinary skill in the art at the time of the invention to provide a tapered portion to the plug member lumen of Freeman et al., as taught by Atkinson, in order to better conform to the tissue passage and therefore provide a more effective sealing function.

Atkinson also teaches a second elongate member **12** insertable through the plug member lumen and is disposed beyond the distal end of the plug member and acts as a location indicator (Figures 11-12; col. 4, lines 27-31). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a second elongate delivery device, as taught by Atkinson, to Brucker in order to facilitate delivery and positioning of the device into a passage through tissue.

5. Claims 26, 31, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Freeman et al.** (U.S. Patent No. **6,306,114**) in view of **Brucker** (U.S. Patent No. **6,296,657**) and **Atkinson** (U.S. Patent No. **6,645,225**), as applied to claims 25, 27, and 33 above, and further in view of **Sepetka et al.** (U.S. Patent No. **5,814,062**).

Claim 26, 31, and 36: Freeman et al. and Brucker disclose the claimed device, including the elongate member able to move the sealing member into a smaller diameter portion of the plug member (Figures 15-16, Freeman et al.), except for an activation element coupled to the elongate member, or the elongate member comprising an expandable and collapsible engagement element engaging and disengaging an interior wall of the plug member, selectively securing to the plug member.

Sepetka et al. teach an activation element or expandable and collapsible engagement element **40** that selectively secures to a plug member **30** during delivery (Figures 4-6). It would have been obvious to one of ordinary skill in the art at the time of invention to provide an activation element or expandable and collapsible engagement element, as taught by Sepetka et al., to Freeman et al., Brucker, and Atkinson in order to provide rapid release times and without exerting any significant force on the implant to avoid significant displacement of the plug during release (see abstract).

6. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Freeman et al.** (U.S. Patent No. **6,306,114**) in view of **Brucker** (U.S. Patent No. **6,296,657**) and **Atkinson** (U.S. Patent No. **6,645,225**), as applied to claim 28 above, and further in view of **Davis** (U.S. Patent No. **6,143,004**).

Claim 29: Freeman et al., Brucker, and Atkinson disclose the claimed device, except for the second elongate member comprising a tubular member including a bleed back lumen, and wherein the location indicator comprises a bleed back port on the distal end of the tubular member, the bleed back port being in communication with the bleed back lumen.

Davis teaches a bleed back lumen **118** and bleed port **114** (Figures 6 and 8). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a bleed back lumen and port, as taught by Davis, to Freeman et al., Brucker, and Atkinson in order to easily verify proper placement of the device within the body (col. 9, lines 43-37).

7. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Freeman et al.** (U.S. Patent No. **6,306,114**) in view of **Brucker** (U.S. Patent No. **6,296,657**) and **Atkinson** (U.S. Patent No. **6,645,225**), as applied to claim 28 above, and further in view of **Sommercorn et al.** (U.S. Patent No. **6,494,848**).

Claim 30: Freeman et al., Brucker, and Atkinson disclose the claimed device except for an expandable member being expandable when the distal end of the second elongate member is disposed within a body lumen for providing tactile feedback of a location of the distal end of the plug member with respect to the body lumen.

Sommercorn et al. teach an expandable member **28** being expandable when the distal end of an elongate member **10** is disposed within a body lumen for providing tactile feedback of a location of the distal end of the device with respect to the body

lumen (Figure 3). It would have been obvious to one of ordinary skill in the art at the time of invention to provide an expandable member for tactile feedback, as taught by Sommercorn et al., to Freeman et al., Brucker, and Atkinson since the mechanism is simple to manufacture and use, as well as facilitates accurate and consistent identification when positioning plug devices during delivery (col. 3, lines 45-51)

Response to Arguments

8. Applicant's arguments filed 09/15/2009 have been fully considered but they are not persuasive.

9. Applicant generally argues that Freeman et al. do not disclose that the sealing member substantially seals the lumen from fluid flow therethrough in either direction since the sealing member is a valve which allows fluid flow in one direction and prevents fluid flow in the other. However, "either direction" is considered as one or another of two directions, and not necessarily both directions, and therefore the sealing member of Freeman et al. reads on this limitation.

10. Applicant also argues that there would be no motivation to combine Freeman et al. with the expandable gel foam of Brucker, since this material would not provide the valve function of Freeman et al. However, Brucker teaches that the expandable foam material seals as it swells but "remains flowable when the device is placed in the wound" (col. 5, lines 7-10), and therefore would not necessarily prevent valve function.

11. In response to applicant's argument that the sealing member of Freeman et al. is not annularly-shaped, or ring-shaped since the sealing member consists of flapper

valves. However, as seen in Figure 7, the sealing member is an annularly-shaped member since it consists of the valve members **54b** disposed around the circumference of the body and when the valve members open, a ring shape is formed.

12. Applicant argues that the coil of material taught by Hermann is not relevant to the design of the sealing member because the screw threads are formed on the outside of the plug body. However, since the plug body itself and the sealing member inside provide functions of sealing within a lumen, it is relevant to this feature. The examiner maintains that it would have been obvious to one of ordinary skill in the art to modify the sealing member of Freeman et al. to have a coil of material for increased traction and therefore a more securely sealed plug.

13. Lastly, applicant argues that Freeman et al. do not disclose the elongate member **160** moving the sealing member **110** into a smaller diameter portion of the plug member in Figures 15-16. However, it is noted that the features upon which applicant relies (i.e., "the elongate member does not engage the sealing member") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. The elongate member does not directly move the sealing member, but rather moves it into a body occlusion which causes movement of the valves due to fluid pressure in the body.

Conclusion

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANE YABUT whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diane Yabut/
Examiner, Art Unit 3734

/Todd E Manahan/

Supervisory Patent Examiner, Art Unit 3734